September 29, 2023

Allmed Medical Products Co., Ltd.
℅ Ivy Wang
Technical Manager
Shanghai Sungo Management Consulting Company Limited
14th Floor, 1500# Central Avenue
Shanghai, Shanghai 200122
China

Re: K221570
Trade/Device Name: Antibacterial bandage
Regulatory Class: Unclassified
Product Code: FRO
Dated: May 31, 2022
Received: May 31, 2022

Dear Ivy Wang:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

David Krause -S

David Krause, Ph.D.
Assistant Director
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K221570

Device Name
Antibacterial bandage

Indications for Use *(Describe)*
Antibacterial bandages are to be applied topically to the skin for the management of minor cuts,minor scrapes. This device is only applicable to adults.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) Summary

<This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirement of 21 CFR 807.92.>

K221570

Date of summary prepared: 2023-09-28

A. Applicant:

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B. Device:

Trade Name: Antibacterial bandage
Common Name: Wound dressing

Regulatory Information
Classification Name: Dressing, Wound, Drug;
Classification: unclassified
Product code: FRO
Regulation Number: NA
Review Panel: General & Plastic Surgery

C. Predicate device:

510(k) Number: K113583
Product Name: Curad Antibacterial bandage

D. Indications for use of the device:

Antibacterial bandages are to be applied topically to the skin for the management of minor cuts, minor scrapes. This device is only applicable to adults.

E. Device Description:

The device, Antibacterial bandage, is to be applied topically to the skin for management of minor cuts, minor scrapes. Antibacterial bandage is made of polyethylene tape, absorbent pad and release paper. The absorbent pad contains 95±10 ug/cm2 (0.8% by weight) benzalkonium chloride. Antibacterial bandage is available in different sizes. The antibacterial bandage is EO sterilized and is for single use only.

Based on in vitro testing, the Benzalkonium chloride effectively reduces microbial growth within the dressing over a maximum use period of 24 hours. No clinical benefit has been studied or demonstrated regarding the Benzalkonium chloride antimicrobial.

F. Technological Characteristics Comparison Table

Provided below is a comparison of the subject device with the predicate device

Table 1 General Comparison

Device	Proposed Device	Predicate Device	Result
510K #	K221570	K113583	-
Trade Name	Antibacterial bandage	Curad Antibacterial Bandage	Similar
Product code	FRO	FRO	Same
Regulation number	NA	NA	Same
Device Classification name	Dressing, wound, drug	Dressing, wound, drug	Same
Indications for use	Antibacterial bandages are to be applied topically to the skin for the management of minor cuts, minor scrapes. This device is only applicable to adults.	Antibacterial bandages are to be applied topically to the skin to help prevent infection in minor cuts, scrapes and burns.	Similar
Configuration	Backing, absorbent pad, release paper	Backing, wound pad	Different
Antimicrobial agent	Benzalkonium chloride 95±10 ug/cm2 (0.8% by weight)	Benzalkonium chloride 0.8%	Same
Material	Antibacterial bandage is made of polyethylene tape, absorbent pad and release paper. The absorbent pad contains 95±10 ug/cm2 (0.8% by weight) benzalkonium chloride.	Anti-bacterial bandage is made of Fabric/polyethylene tape, and absorbent pad. Absorbent pad contains 0.8% benzalkonium chloride.	Similar
Anatomical location	For use on minor cuts, minor scrapes.	For use on minor cuts, scrapes, and burns.	Similar
OTC use	Yes	Yes	Same
Sterile method	EO sterilization	EO sterilization	Same
Singe Use	Yes	Yes	Same
Biocompatibility	Complies with ISO 10993-1 for	Comply with ISO 10993	Same

	limited contact duration on breached/compromised skin		

Substantial equivalence discussion:

The Antibacterial Bandage is compared to the predicate device with respect to indications for use, materials, antimicrobial agent, BZK concentration, etc. According to the comparison information, most of the characteristics of the subject device are the same as the predicate device, some of the characteristics are similar, one is different, but none of them will cause different safety or effectiveness issues.

G. Non-Clinical Test Conclusion

Non-clinical tests were conducted to verify that the proposed device met all design specifications as was same to the predicate device. The test results demonstrated that the proposed device complies with the following standards.

- Biocompatibility:
  - Cytotoxicity,
  - Sensitization,
  - Intracutaneous reactivity,
  - Systemic Toxicity,
  - Material-mediated Pyrogenicity
  - Endotoxin testing
- Sterilization Testing

ISO 11135:2014, Sterilization of health-care products - Ethylene oxide - Requirements for the development, validation and routine control of a sterilization process for medical devices.

- Shelf Life Testing

ASTM F1980-16, Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Device

Real time ageing study was done to demonstrate the device stability under market conditions.

- Storage and Transport Testing

ASTM 4169-16, Standard Practice for Performance Testing of Shipping Containers and Systems

- AATCC 100: 2019, Antibacterial Finishes on Textile Materials
- Animal studies

A porcine wound healing study was carried out to evaluate the cytotoxicity of the subject device. The study demonstrated that there was no significant difference between the subject device and the predicate device in the terms of wound healing performance.

H. Clinical Test Conclusion

No clinical study is included in this submission.

I. Conclusion

The conclusions drawn from the nonclinical tests demonstrate that the subject device is as safe, as effective, and performs as well as the legally marketed predicate device K113583.